

**EWG M2 Recommendation to the ICH Steering Committee**  
**Electronic Standards for the Transfer of Regulatory Information (ESTRI)**  
**General - Recommendation 1.2**

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01MAY1996

**Title:** General 1.2 - Gateway Recommendation for the Electronic Transfer of Regulatory Information (ESTRI Gateway)

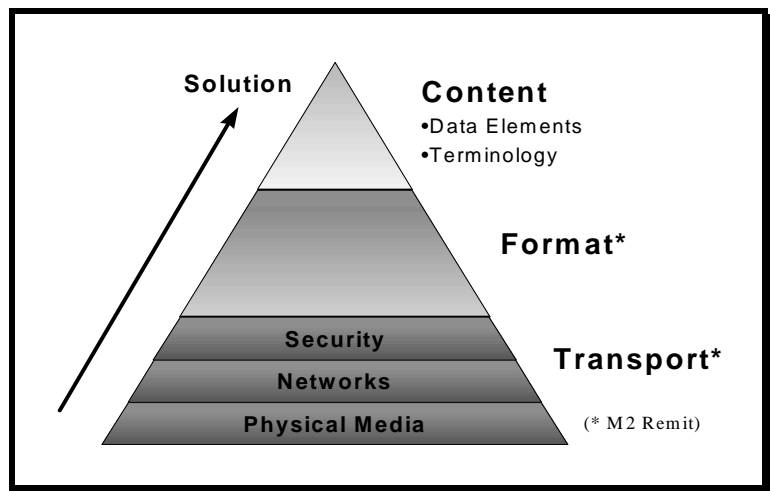
**Date:** 1 May 1996

**Background:**

Electronic transfer of regulatory information offers the potential for significant time and resource savings for both Industry and Regulatory Authorities. However, the lack of internationally accepted (and implemented) standards for both the content and transport of this information poses significant obstacles to achieving this objective. Differences exist in the technical environments of Industry and Regulatory Authorities. In addition, there is not agreement concerning the information to be collected and reported nor the terminology to be used in describing this information.

A complete "solution" to electronic regulatory communications consists of several different, but complementary, components (see Figure 1). These different components are currently being addressed by the various ICH Expert Working Groups (EWG). For example, in the case of adverse event reports:

- o Content
  - o Data elements - E2b, E2c
  - o Terminology - M1
- o Format - M2
- o Transport - M2



The result of the combined effort of these different EWGs will be the definition of standards which will enable the electronic transfer of regulatory information.

**ESTRI Gateway:** The M2 EWG has considered a number of alternatives and has concluded that an appropriately configured gateway provides the only viable solution for the electronic transfer of regulatory information. This gateway concept for communication between parties exchanging information is essential to the success of this effort. The EWG considers this result a major achievement.

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As illustrated in Figure 2, this concept, referred to as the ESTRI Gateway, will enable Regulatory Authorities to electronically exchange and share regulatory information, beginning with safety information. Based on the internationally accepted standards, all communication partners can extract information from internal databases, create the regulatory communication, and send to the receiver with confidence that it will be received intact, protected and useable by the receiver, regardless of the technology of their internal systems.

The ESTRI Gateway is a data exchange service which will support regulatory communication based upon any of the recommended standards.

**Definition:** An ESTRI Gateway is compliant with the recommended core standards. Regulatory Authorities will implement the multiple standards and will be able to transmit to and receive information from all other parties who have implemented such an ESTRI Gateway, regardless of their technical infrastructure. Where multiple standards have been recommended, Industry must implement at least one of the recommended standards in order to communicate with any Regulatory Authority.

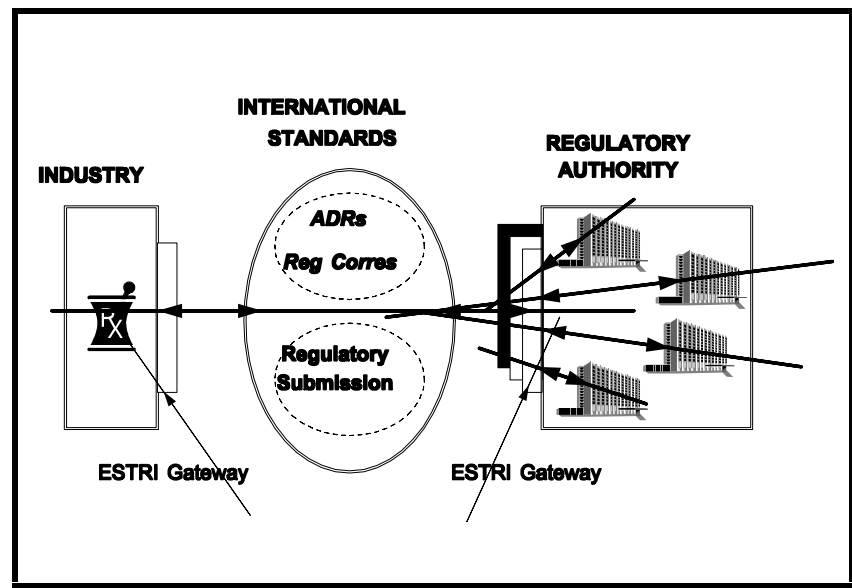


Figure 2

This ESTRI Gateway will be based on individual standards addressing different aspects of the regulatory communication. The following is a list of areas which are currently being addressed by the EWG. Other standards areas will be addressed by the EWG in developing a total solution for regulatory communication.

- o Physical Media
- o Networks
- o Security
- o Format

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It is the intention of the EWG to keep the number of recommendations to a minimum, i.e. a single standard should be recommended where possible.

The on-going identification and recommendation of standards will allow the ESTRI Gateway to be implemented and to evolve in a systematic manner to accommodate other aspects of regulatory communication - through a single point of implementation and maintenance.

**Recommendation:**

The EWG recommends that the ESTRI Gateway concept be adopted by the Steering Committee. The EWG further recommends that the Steering Committee approves the following **definition of** the ESTRI Gateway concept:

- o In each Region the Regulatory Authorities (i.e., EU, FDA, and MHW) will implement at least one ESTRI Gateway for communication with Industry and with other Authorities which consists of all core standards and functionality required to support the standards. In those instances where multiple standards are recommended, the Regulatory Authority will implement all recommended standards.
- o Industry desiring to communicate regulatory information electronically with Authorities must implement at least one of the multiple standards.

**Conditions:**

- o In those cases where multiple standards have been adopted for the same functionality (e.g., SMTP/MIME and X.400 for messaging), the Regulatory Authorities will provide the necessary infrastructure within their ESTRI Gateway to accommodate all of the multiple standards. This will allow each Authority to receive regulatory communications from any Industry ESTRI Gateway, and it will also allow the Authority to implement a single standard within their organization or member organizations. However, the aim should be to restrict the standards adopted to a minimum.
- o This approach will accommodate instances in which a Regulatory Authority may choose to support a specific language implementation of a standard (e.g., Japanese and English) if their regulations require submission in that language.
- o These recommendations will be complemented and validated within the performance of an appropriate ESTRI Gateway testing in the three Regions

**Remarks:**

None.

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